

REMARKS

1. Status of the Claims and Formal Matters

Claims 1-2, 4-5 and 7-16 are pending in this application. Claims 3 and 6 were previously canceled and claims 11-12 and 15 were previously withdrawn from further consideration. Claims 1-2, 4-5 and 7-10 and 14 are amended. Claims 17-21 are new. Upon entry of these amendments, claims 1-2, 4-5 and 7-21 are pending with claims 1-2, 4-5, 7-10, 13-14 and 16-21 under active consideration. Applicants respectfully request entry of the remarks made herein into the file history of the present application.

Claim 1 is amended in response to the restriction requirement to recite an "An isolated nucleic acid comprising the sequence of SEQ ID NO: 1," support for which may be found at SEQ ID NO: 1 and claim 1 as originally filed.

Claim 2 is amended to recite an "An isolated RNA of 18 to 24 nucleotides encoded by the nucleic acid of claim 1," support for which may be found in claim 1 as originally filed.

Claim 4 is amended to replace "The gene of claim 1" with "A gene encoding the nucleic acid of claim 1," support for which may be found in claim 1 as originally filed.

Claim 5 is amended to correct dependency and antecedent basis.

Claim 7 is amended to correct antecedent basis.

Claim 8 is amended to correct dependency and antecedent basis. Claim 8 is also amended to recite an RNA that "is at least 50% complementary to a binding site sequence of 18 to 24 nucleotides of a target human gene and wherein the binding site sequence," support for which may be found at Table 1 and paragraph [0011].

Claim 9 is amended to correct antecedent basis.

Claim 10 is amended to correct antecedent basis.

Claim 14 is amended to correct antecedent basis.

New claim 17 recites an isolated RNA of about 50 to 77 nucleotides encoded by the nucleic acid of claim 1, support for which may be found in claim 1 as originally filed and SEQ ID NO: 1.

New claim 18 recites an isolated RNA of about 22 nucleotides encoded by the nucleic acid of claim 1, support for which may be found at paragraph [0067].

New claim 19 recites a nucleic acid complementary to the nucleic acid of claim 1, support for which may be found at paragraphs [0016] and [0034].

New claim 20 recites a nucleic acid complementary to the nucleic acid of claim 2, support for which may be found at paragraphs [0016] and [0034].

New claim 21 recites a nucleic acid complementary to the nucleic acid of claim 4, support for which may be found at paragraphs [0016] and [0034].

2. Election

At page 2 of the Office Action, the Examiner requires restriction to a single sequence. The Examiner alleges that each sequence is patentably distinct because they are unrelated sequences. The Examiner further alleges that the previous waiver for up to 10 elected nucleic acid sequences is effectively impossible to reasonably implement because an election of more than one nucleic acid sequence would result in an undue search burden. Applicant respectfully traverse the sequence election requirement. Applicant respectfully requests reconsideration and modification of the restriction requirement in compliance with *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). In compliance with 37 C.F.R. §1.143 Applicant provisionally elects SEQ ID NO: 1 for prosecution.

a. Error In Restriction Requirement

In spite of nucleotide sequences being presumed to represent independent and distinct invention subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*, the Director decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996); MPEP 803.04. As set forth at MPEP 803.04:

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.**

...

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may

necessitate that the reasonable number of sequences to be selected be less than ten. (emphasis added)

It is clear from the above passage that the Applicant is entitled to have up to ten independent and distinct nucleotide sequences examined in a single application unless the Examiner is able to show that the instant application is an “exceptional case.” The only grounds that the Examiner has asserted for this application being an exceptional case is that there has been a “multitude of sequence submissions.” *See* page 2 of Office Action. Importantly, the Examiner fails to show, or even allege, that any of the disclosed sequences rise to the level of an “exceptional case.” Apparently, the Examiner is instead claiming that it is the disclosure of over 10^5 sequences in the instant application that would cause an undue search burden if more than one sequence is elected.

Regardless of the number of sequences disclosed in the application, an election of ten disclosed sequences would produce the same search burden on the Examiner as if the application were filed disclosing only the same ten sequences with no other sequences. In other words, only ten sequences would be required to be searched. In view of the Examiner failing to show that the claimed subject matter is of a sufficient complex nature to qualify as an exceptional case, Applicant respectfully requests reconsideration and modification of the sequence election requirement in compliance with *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

3. Conclusion

If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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APPENDIX A

For the convenience of the Examiner, Applicant presents herewith a copy of the claims that will be pending upon entry of the present amendments.

1. (currently amended) An isolated nucleic acid comprising the sequence of SEQ ID NO: 1.
2. (currently amended) An isolated RNA of 18 to 24 nucleotides encoded by the nucleic acid of claim 1.
3. (canceled)
4. (currently amended) A gene encoding the nucleic acid of claim 1, wherein said gene is maternally transferred by a cell to at least one daughter cell of said cell.
5. (currently amended) The RNA of claim 2, wherein expression of said RNA is capable of promoting expression of a target human gene.
6. (canceled)
7. (currently amended) The RNA of claim 2 wherein said encoded RNA is capable of modulating expression of a target human gene.
8. (currently amended) The RNA of claim 2 wherein the RNA is at least 50% complementary to a binding site sequence of 18 to 24 nucleotides of a target human gene and wherein the binding site sequence is located in an untranslated region of RNA encoded by said target gene.
9. (currently amended) The RNA of claim 8 wherein the binding site sequence is located in the 3' untranslated region of the RNA encoded by said target human gene.
10. (currently amended) A vector comprising the nucleic acid of claim 1.
11. (withdrawn) A method of selectively inhibiting translation of at least one gene, comprising introducing the vector of claim 10 into a cell.
12. (withdrawn) A method according to claim 11 and wherein said introducing comprises utilizing RNAi pathway.
13. (previously amended) A gene expression inhibition system comprising the vector of claim 10 and a means for inserting said vector into a cell.
14. (currently amended) A probe comprising the nucleic acid of claim 1.